

Attorney Docket No. P70594US0  
Application No. 10/535,655

**Remarks/Arguments:**

Claims 8-21, newly presented, are pending.

Claims 1-7 are canceled, without prejudice or disclaimer, with claims 6 and 7 being canceled pursuant to restriction.

New claims 8-21 are presented, *inter alia*, to both (1) add method steps, to overcome the §112, ¶1, rejection (explained more fully below) and (2) more clearly define the invention.

In accordance with new claims 8-21, original claim 1 is divided into one generic claim (claim 8) and two sub-generic claims (claims 12 and 17)—generic claim 8 being independent, sub-generic claim 12 being dependent on claim 8, and sub-generic claim 17 being dependent on claim 12. New claims corresponding to original claims 2-5 are presented hereby, dependent on each of claim 8 (claims 9-11), claim 12 (claims 13-16), and claim 17 (claims 18-21).

New claim 8 defines the invention most broadly as a "method for inducing release of  $^{13}\text{CO}_2$  in exhaled air." This broadly defined method is limited by two method steps—"intravenous administration of secretin and oral administration of a  $^{13}\text{C}$ -triglyceride."

New claim 12 essentially corresponds to original claim 1 as a "method for measuring an induced release of  $^{13}\text{CO}_2$ ." New claim 12 is limited as comprising two method steps: the first method step being "inducing the release of  $^{13}\text{CO}_2$  according to [new] claim 8" with the second step being "measuring the release of  $^{13}\text{CO}_2$  in the exhaled air . . . before and after intravenous administration of secretin and before and after oral administration of the  $^{13}\text{C}$ -triglyceride."

Attorney Docket No. P70594US0  
Application No. 10/535,655

New claim 17 essentially corresponds to that aspect of original claim 1 relating the induced release of  $^{13}\text{CO}_2$  with pancreatic metabolism. Claim 17 contains two method steps: (1) "measuring an increase of  $^{13}\text{CO}_2$  in the exhaled air of a subject according to claim 12" and (2) "comparing (i) the increase of  $^{13}\text{CO}_2$  in the exhaled air of the subject with (ii) a previously measured increase of  $^{13}\text{CO}_2$  in the exhaled air of a healthy subject," this comparison leading to a "diagnosis of exocrine pancreatic insufficiency (EPI)," when it shows "a delayed or reduced release of  $^{13}\text{CO}_2$  in the subject as compared to the healthy subject."

Claims 1 and 3-5 were objected to for allegedly containing informalities, with the statement of objection identifying, specifically, the instances of alleged informalities. Present claims 8-21 reflect changes to claims 1 and 3-5, which resolve all of the identified informalities, set forth in the statement of objection. Withdrawal of the objection appears to be in order.

Claims 1-5 were rejected under 35 USC 112, first paragraph, for allegedly lacking enablement. Reconsideration is requested.

The principle of measuring the metabolism of the pancreas is known, e.g., as evidenced by Löser et al. (1998), of record, which is cited in the present specification (page 2, 3<sup>rd</sup> complete paragraph, and page 4, 1<sup>st</sup> paragraph).

During testing the  $^{13}$ triglyceride is metabolized by the body (as are normal triglycerides), wherein pancreatic enzymes are active. Based on the metabolic processing  $^{13}\text{CO}_2$  is liberated and exhaled. Exocrine pancreatic insufficiency (EPI) reduces the production of enzymes in the pancreas (present specification, page 1, paragraph 2) and, therefore, delays the production of  $^{13}\text{CO}_2$ .

Attorney Docket No. P70594US0  
Application No. 10/535,655

It was not known to administer secretin in connection with the test meal. Attention is especially directed to the instant specification Example and Figures 1 and 2. Taken together with what was known in the art, the subject application provides more than ample guidance, for the person skilled in the art, to make and use the presently claimed invention—including how to analyze the data obtained from the measurement—and, thereby, satisfy the requirements for enablement under §112, ¶1. In "satisfying the enablement requirement, an application need not teach, and preferably omits, that which is well known in the art." *Staehelein v. Secher*, 24 USPQ2d 1513, 1516 (BPA&I 1992). A "patent need not disclose, and preferably omits, that which is well known in the art." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986).

Since any teachings necessary to satisfy the enablement requirements of §112, ¶1, that are not expressly described in the subject application represent what is already "well known in the art," the "application need not teach, and preferably omits, that which is well known in the art." *Staehelein*, 24 USPQ2d at 1516. Withdrawal of the rejection under §112, ¶1, for allegedly lacking enablement appears to be in order.

Claims 1-5 were rejected under 35 USC 112, second paragraph, as allegedly being indefinite. Reconsideration is requested.

According to the statement of rejection (Office Action, page 5) (emphasis added), the rejected claims are allegedly indefinite for failing "to set forth how the metabolism of the pancreas is measured." The statement of rejection confuses the function of the claims, on the one hand, with the function of the specification, on the other.

Attorney Docket No. P70594US0  
Application No. 10/535,655

The claims define the legal limits of the invention, the specification details how to make and use the invention. *In re Roberts*, 176 USPQ 313, 315 (CCPA 1973). Since it is the function of the specification—not the claims—to detail how to make and use the invention, the claims were improperly rejected for failing to recite how the metabolism of the pancreas is measured. *Roberts*, 176 USPQ at 315.

The §112, ¶2, rejection is also based on there being no method step connecting the outcome of the method with the purpose recited in the claim preamble. This is resolved—in present claim 17—by adding the final step

wherein a delayed or reduced release of  $^{13}\text{CO}_2$  in the subject as compared to the healthy subject indicates a diagnosis of EPI in the subject.

For the foregoing reasons the rejection under §112, ¶2, is overcome. Withdrawal of the rejection appears to be in order.

Applicant wishes to thank the examiner for the indication of allowable subject matter.

***Request for Examiner's Initialed Form PTO 1449***

An Information Disclosure Statement (IDS), including completed form PTO 1449 and copies of the cited references, was filed in the PTO. The submitted PTO form 1449, initialed by the Examiner, was attached to the instant Office Action; however, a line was drawn through the cited DE-C-44 26 204, indicating that the reference was not considered by the examiner, because an explanation of its relevance was allegedly not provided.

Attorney Docket No. P70594US0  
Application No. 10/535,655

The requisite statement of relevance does not appear strictly within the four corners of the filed IDS. Nevertheless, the requisite statement does appear in the paragraphs bridging pages 1 and 2 of the specification (emphasis added), i.e.:

A pancreatic functional test in which amylase is determined mainly has been described in DE-C-44 26 204. In this test, natural corn starch is administered and, after metabolization, secreted through the exhaled air as  $^{13}\text{C}$ -enriched carbon dioxide, and analyzed. The test is based on the fact that corn starch is naturally enriched with  $^{13}\text{C}$  atoms.

A disadvantage of this test is that only severe degree exocrine pancreatic insufficiency can be determined thereby. Inter alia, this is due to the fact that the pancreas is not the only source of amylase and therefore the test is interfered with by amylase in the saliva and gastric secretion, cf. Löser et al., Z. Gastroenterol. 1997; 35: 187-194).

For the examiner's convenience, applicant also provides, herewith, an English language abstract of the cited reference.

Accordingly, the Examiner is requested to mark and initial the submitted Form PTO 1449 to show that the reference at issue was considered and return the initialed Form so marked to applicant's undersigned representatives. Also for the examiner's convenience, attached hereto is a copy of the previously submitted Form PTO 1449.

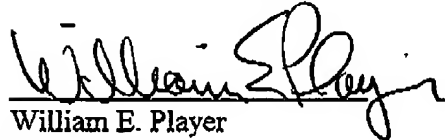
Attorney Docket No. P70594US0  
Application No. 10/535,655

Favorable action is requested.

Respectfully submitted,

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## Diagnostic and its use

Publication number: DE4426204  
Publication date: 1995-01-26  
Inventor: AYGEN SITGE DR (DE)  
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Classification:  
- international: A61K51/06; A61K51/02; (IPC1-7):  
A61K49/00; A61B10/00;  
C12Q1/40; G01N33/60; G21H5/02  
- European: A61K51/06  
Application number: DE19944426204 19940723  
Priority number(s): DE19944426204 19940723;  
DE19934324949 19930724

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### Abstract of DE4426204

Diagnostic, containing substances with  $^{13}\text{C}$ -enriched atoms, which after metabolism in the body are excreted via the respiratory air as  $^{13}\text{C}$ -enriched carbon dioxide, for the determination of the functional efficiency of the pancreas by use of maize starch.

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